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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Russell G. Higuchi  
SERIAL NO. : 07/695,201 GROUP ART UNIT: 1814  
FILED : May 2, 1991 EXAMINER: R. Prouty  
DOCKET NO. : 2599  
TITLE : HOMOGENEOUS METHODS FOR NUCLEIC ACID AMPLIFICATION AND DETECTION

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56, §1.97, AND §1.98

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Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

The Examiner may find the following references and information, submitted in accordance with the duty of the disclosure under 37 C.F.R. §1.56, §1.97, and §1.98, material in the examination of the above-identified application. Copies of the references listed below and on the attached P.T.O. 1449 form are provided. The Examiner is requested to make these references of official record in the application. The publications listed below were cited in the European Search Report of the foreign equivalent of the present application.

The present invention provides for a means of simultaneously amplifying and detecting amplified target nucleic acid. Simultaneous amplification and detection is made possible through the use of DNA binding agents which give a photodetectable signal when bound to duplexed nucleic acid. Through the use of photodetectors, it is possible to measure the amplification of nucleic acid while the reaction is proceeding.

1. European Patent Publication No. 487,218
2. PCT Patent Publication No. WO 90/15881
3. Isaacs *et al.*, January, 1991, Nucleic Acids Research 19(1):109-116

European Patent No. 487,218 is provided for Examiner's convenience, although the publication is not prior art to the present application. The European patent publication was

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this 19 day of January, 1994  
By Russell G. Higuchi

published subsequent to the filing date of the present application. Applicants are unaware of a U.S. application that corresponds to the European patent publication. However, having brought this matter to the Examiner's attention, Applicants believe that the Examiner has means for determining whether a corresponding U.S. counterpart does exist that may be relevant to the prosecution of the present application.

Isaacs *et al.* describe post-PCR sterilization process.

Although PCT Patent Publication No. WO 90/15881 is provided in French, a concise explanation of the publication as described in the abstract is as follows. PCT Patent Publication No. WO 90/15881 discloses a method for detecting specific nucleic acid sequences which are present in a biological sample, comprising at least one enzymatic amplification. Detection is carried out, after placing the biological samples in a solution in order to extract the nucleic acid, by enrichment with target sequences by putting the biological samples into contact with at least one pair of appropriate primers, followed by at least one appropriate dilution of the obtained enrichment amplifying solution, and by putting a fraction of this solution into contact with at least one pair of primers, followed by the detection of the obtained double-strand target nucleic acid copies. Thus, the method, as described in Figure 1 of the publication, is a nested priming amplification procedure followed by detection using a solid support capture technique.

This Supplemental Information Disclosure Statement under 37 C.F.R. §1.56, §1.97, and §1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that this citation constitutes prior art under 35 U.S.C. §102 and §103.

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Since the Supplemental Information Disclosure Statement is submitted after the first Office Action on the merits and after three months of the filing date for the captioned application, the Commissioner is hereby authorized to charge the \$200.00 filing fee or any associated fees to Deposit Account No. 08-2525.

Respectfully submitted,

By:

  
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